

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TEXAS  
MARSHALL DIVISION**

**CENTOCOR, INC. and  
NEW YORK UNIVERSITY,**

**Plaintiffs,**

**V.**

**ABBOTT LABORATORIES, ABBOTT  
BIORESEARCH CENTER, INC., and  
ABBOTT BIOTECHNOLOGY, LTD.**

## Defendants.

**CIVIL ACTION NO. 2:07CV139**

**NOTICE OF FILING OF P.R. 4-5(d) JOINT CLAIM CONSTRUCTION CHARTS**

Plaintiffs and Defendants hereby respectfully submit their Patent Rule 4-5(d) Joint Claim Construction Charts. An electronic WordPerfect format of these charts is being sent to the Court. The parties have met and conferred in accordance with the Court's Order and the attached chart sets forth the claim terms and phrases that have been agreed to and those that are still in dispute among the parties. If further agreements are made, the parties will immediately notify the Court.

Dated: February 12, 2009

Respectfully submitted,

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ABBOTT BIOTECHNOLOGY LTD.**

**CERTIFICATE OF SERVICE**

I hereby certify that all counsel of record, who are deemed to have consented to electronic service are being served this 12 day of February, 2009, with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(a)(3). Any other counsel of record will be served by electronic mail, facsimile transmission and/or first class mail on this same date.

/s/ Angela Verrecchio

Angela Verrecchio

# **EXHIBIT A**

*Centocor, Inc. and New York University v. Abbott Laboratories, et al.*  
**Civil Action No. 2:07-CV-139**

U.S. Patent Nos. 7,070,775 and 7,276,239  
**Patent Rule 4-5(d) Joint Claim Construction Chart**

Claim Term/Phrase	Centocor's Construction	Abbott's Construction	Court's Construction
<b>Claim 1 of the 775 Patent:</b>  An isolated <b>recombinant<sup>1</sup> anti-TNF-<math>\alpha</math> antibody<sup>2</sup></b> or antigen binding fragment thereof, said antibody comprising a human constant region, wherein said antibody or antigen binding fragment (i) <b>competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-<math>\alpha</math><sup>3</sup></b> , and (ii) <b>binds to a neutralizing epitope<sup>4</sup> of human TNF-<math>\alpha</math> in vivo with an affinity of at least <math>1 \times 10^8</math> liter/mole, measured as an association constant (K<sub>a</sub>), as determined by Scatchard analysis.<sup>5</sup></b>	<u><b>recombinant</b></u>  Encoded by DNA made with recombinant DNA technology, e.g., encoded by a gene that was built by splicing DNA	<u><b>recombinant</b></u>  A "recombinant" anti-TNF $\alpha$ antibody is an antibody originally developed through artificial <i>in vitro</i> DNA manipulation techniques and not substantially by natural immunization techniques	
	<u><b>anti-TNF-<math>\alpha</math> antibody</b></u>  An immunoglobulin protein that binds to TNF- $\alpha$	<u><b>anti-TNF-<math>\alpha</math> antibody</b></u>  A murine or chimeric antibody (combining DNA sequences from different species) that binds to human TNF $\alpha$	

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	<p><b><u>competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-<math>\alpha</math></u></b></p> <p>Competes with A2 (ATCC Accession No. PTA-7045) for binding to human TNF-<math>\alpha</math></p>	<p><b><u>competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-<math>\alpha</math></u></b></p> <p>ATCC PTA-7045 is a hybridoma deposited with the American Type Culture Collection. The product of the ATCC PTA-7045 includes the A2 antibody, which binds to human TNF<math>\alpha</math>. An antibody "competitively inhibits" A2 if, in a standard ELISA or equivalent assay:</p> <p>(i) the antibody blocks binding of the antibody product of ATCC PTA-7045 to human TNF<math>\alpha</math> at least as well as the hybridoma product blocks itself</p>	



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		<p style="text-align: center;">-AND-</p> <p>(ii) the blocking of the ATCC PTA-7045 product is due to the test antibody binding the same epitope of TNF<math>\alpha</math> as the antibody product of ATCC PTA-7045. An "epitope" consists of amino acid residues on the antigen to which an antibody binds</p>	
	<p style="text-align: center;"><b><u>neutralizing epitope</u></b></p> <p>Portion of TNF-<math>\alpha</math>, which, when bound by an antibody, results in a loss of biological activity of TNF-<math>\alpha</math></p>	<p style="text-align: center;"><b><u>neutralizing epitope</u></b></p> <p>Binding of the anti-TNF<math>\alpha</math> antibody is to a "neutralizing epitope" if binding results in a loss of biological activity associated with the human TNF<math>\alpha</math></p>	

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	<p><u><b>binds to a neutralizing epitope of human TNF-<math>\alpha</math> in vivo with an affinity of at least <math>1 \times 10^8</math> liter/mole, measured as an association constant (<math>K_a</math>)m as determined by Scatchard analysis</b></u></p> <p>Results in a loss of biological activity when it binds to human TNF-<math>\alpha</math> in vivo; and associates (binds) with human TNF-<math>\alpha</math> with an affinity of at least <math>1 \times 10^8</math> liter/mole as calculated using a method for data analysis known as a Scatchard analysis</p>	<p><u><b>binds to a neutralizing epitope of human TNF-<math>\alpha</math> in vivo with an affinity of at least <math>1 \times 10^8</math> liter/mole, measured as an association constant (<math>K_a</math>)m as determined by Scatchard analysis</b></u></p> <p>Binding of the anti-TNF<math>\alpha</math> antibody is to a "neutralizing epitope" if binding results in a loss of biological activity associated with the human TNF<math>\alpha</math>, and further binds to the epitope in the organism with an affinity of at least <math>K_a=1 \times 10^8</math> liter/mole as measured in the living organism using Scatchard Analysis.</p>	

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<b>Claim Term/Phrase</b>	<b>Centocor's Construction</b>	<b>Abbott's Construction</b>	<b>Court's Construction</b>
<p><b>Claim 2 of the 775 Patent:</b></p> <p>The antibody or antigen-binding fragment of claim 1, wherein the antibody or antigen-binding fragment comprises a human constant region and a <b>human variable region</b>.<sup>6</sup></p>	<p><b><u>human variable region</u></b></p> <p>A variable region that is encoded by a gene derived from human DNA</p>	<p><b><u>human variable region</u></b></p> <p>An antibody variable region (<math>V_H</math> and <math>V_L</math> gene products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species.</p>	
<p><b>Claim 3 of the 775 Patent:</b></p> <p>The antibody or antigen-binding fragment of claim 1, which comprises at least one <b>human light chain</b><sup>7</sup> and at least one <b>human heavy chain</b>.<sup>8</sup></p>	<p><b><u>human light chain</u></b></p> <p>Light chain encoded by a gene derived from human DNA</p>	<p><b><u>human light chain</u></b></p> <p>An antibody light chain (<math>C_L</math> and <math>V_L</math> gene products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species.</p>	

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	<p style="text-align: center;"><b><u>human heavy chain</u></b></p> <p>Heavy chain encoded by a gene derived from human DNA</p>	<p style="text-align: center;"><b><u>human heavy chain</u></b></p> <p>An antibody heavy chain (C<sub>H</sub> and V<sub>H</sub> gene products) that has an amino acid sequence predominantly derived from human genetic sequences with complementarity determining regions (CDRs) grafted from a rodent or other non-human species.</p>	

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<b>Claim 9:</b>  The antibody or antigen-binding fragment of claim 1, which has <b>specificity</b> for a neutralizing epitope of human TNF- $\alpha$ .	<u><b>specificity</b></u>  “Specificity” is the property of antibodies which enables them to react with a particular antigen. In the context of this claim, the term “specificity” is used to describe the antibody or antigen binding fragment as one that binds to human TNF- $\alpha$ but not human TNF- $\beta$	<u><b>specificity</b></u>  Specificity (for a neutralizing epitope of human TNF $\alpha$ ) means that the antibody binds to a neutralizing epitope of human TNF $\alpha$ and chimpanzee TNF $\alpha$ but not to TNF $\alpha$ of other species (e.g. baboon, rhesus monkey, cynomolgous monkey, pig, rabbit, rat, or mouse)	
<b>Claim 11 of the 239 Patent:</b>  The antibody or antigen-binding fragment of claim 9, wherein said binding of the antibody or antigen-binding fragment to human TNF $\alpha$ <b>inhibits a pathological activity of human TNF <math>\alpha</math>.</b>	<u><b>inhibits a pathological activity of human TNF<math>\alpha</math></b></u>  Inhibits a TNF- $\alpha$ -mediated biological activity associated with a clinical problem such as disease, infection and/or malignancy	<u><b>inhibits a pathological activity of human TNF<math>\alpha</math></b></u>  Inhibits a biological activity such as cytotoxicity, inflammation, or other activity associated with human TNF $\alpha$ mediated disease or damage.	

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<p><b>Claim 14 of the 239 Patent:</b></p> <p>The anti-TNF<math>\alpha</math> antibody or antigen-binding fragment thereof of claim 9, which is <b>produced recombinantly</b>.</p>	<p><b><u>produced recombinantly</u></b></p> <p>Produced in a recombinant host cell, e.g., produced from a source (organism or cell line, for example) that includes a gene that was built by splicing DNA</p>	<p><b><u>produced recombinantly</u></b></p> <p>A "recombinant anti-TNF<math>\alpha</math> antibody" is "produced recombinantly" if the antibody is a product of DNA that has been artificially introduced into a cell so that it alters the genotype and phenotype of the cell and is replicated along with the natural DNA.</p>	
<p><b>Claim 10 of the 239 Patent:</b></p> <p>The antibody or antigen-binding fragment of claim 9, which binds with <b>high affinity</b> to a neutralizing epitope of human TNF<math>\alpha</math> in vivo.</p>	<p><b><u>high affinity</u></b></p> <p>Agreed</p>	<p><b><u>high affinity</u></b></p> <p>Agreed</p>	<p>An affinity of at least <math>1 \times 10^8</math> expressed as an association constant (<math>K_a</math>)</p>

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1. The term “recombinant” appears in claims 1 and 13 of the 775 Patent and the dependent claims thereto, and in claims 3 and 9 of the 239 Patent, and the dependent claims thereto. The Parties agree that the term “recombinant” should be construed consistently in every claim in which it appears.
2. The term “anti-TNF- $\alpha$  antibody” appears in claims 1 and 13 of the 775 Patent and the dependent claims thereto, and in claims 3 and 9 of the 239 Patent, and the dependent claims thereto. The Parties agree that the term “anti-TNF- $\alpha$  antibody” should be construed consistently in every claim in which it appears.
3. The phrase “competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF- $\alpha$ ” appears in claims 1 and 13 of the 775 Patent and the dependent claims thereto, and in claim 9 of the 239 Patent, and the dependent claims thereto. The phrase “competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF- $\alpha$ ” also is incorporated by reference in claim 3 of the 239 Patent. The Parties agree that the phrase “competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF- $\alpha$ ” should be construed consistently in every claim in which it appears.
4. The term “neutralizing epitope” appears in claims 1 and 13 of the 775 Patent and the dependent claims thereto, and in claim 10 of the 239 Patent. The Parties agree that the term “neutralizing epitope” should be construed consistently in every claim in which it appears.
5. The phrase “binds to a neutralizing epitope of human TNF- $\alpha$  in vivo with an affinity of at least  $1 \times 10^8$  liter/mole, measured as an association constant ( $K_a$ ), as determined by Scatchard analysis” appears in claims 1 and 13 of the 775 Patent, and the dependent claims thereto. The Parties agree that the phrase “binds to a neutralizing epitope of human TNF- $\alpha$  in vivo with an affinity of at least  $1 \times 10^8$  liter/mole, measured as an association constant ( $K_a$ ), as determined by Scatchard analysis” should be construed consistently in every claim in which it appears.
6. The term “human variable region” appears in claims 2 and 14 of the 775 Patent. The Parties agree that the term “human variable region” should be construed consistently in each claim in which it appears.

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7. The term “human light chain” appears in claims 3 and 15 of the 775 Patent. The Parties agree that the term “human light chain” should be construed consistently in each claim in which it appears.
8. The term “human heavy chain” appears in claims 3 and 15 of the 775 Patent. The Parties agree that the term “human heavy chain” should be construed consistently in each claim in which it appears.